

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

OAKWOOD LABORATORIES, L.L.C.
7670 First Place, Suite A
Oakwood Village, Ohio 44146,

Plaintiff,

v.

DR. BAGAVATHIKANUN THANOO
4 Margaret Drive
Somerset, New Jersey 08873,

AUROMEDICS PHARMA LLC
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, Delaware 19808,

AUROBINDO PHARMA U.S.A., INC.
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, Delaware 19808,

AUROBINDO PHARMA LTD.
Plot No. 2, Maitrivihar
Ameerpet
Hyderabad-500038
Telangana, India,

Defendants.

Case No.: 3:17-cv-05090-PGS-LHG

Judge: Peter G. Sheridan

**THIRD AMENDED
COMPLAINT FOR MONETARY AND
INJUNCTIVE RELIEF**

(Jury Demand Endorsed Hereon)

Pursuant to the Court's Memorandum and Order dated January 31, 2019 (Docket No. 67), Plaintiff, Oakwood Laboratories, L.L.C. ("Oakwood"), for its Third Amended Complaint against Dr. Bagavathikanun Thanoo ("Dr. Thanoo"), AuroMedics Pharma LLC ("AuroMedics"), Aurobindo Pharma U.S.A., Inc. ("Aurobindo USA"), and Aurobindo Pharma Ltd. ("Aurobindo"), alleges as follows:

PARTIES

1. Oakwood is a limited liability company with its principal place of business located in Cuyahoga County, Ohio. Oakwood is owned by members Edward C. Smith (resident of Cleveland Heights, Ohio), Mark T. Smith (resident of Pittsburgh, Pennsylvania), Mary S. Podles (resident of Baltimore, Maryland), Leon Podles (resident of Baltimore, Maryland), Sauganash Foundation, Rockside Foundation, Fairmount Investors, L.L.L.P., Eastern Shore-Mentor Limited Partnership, Green Dolphin Charlies Limited Partnership, Green Dolphin James Limited Partnership, Green Dolphin John Limited Partnership, Green Dolphin Thomas Limited Partnership, Green Dolphin Sarah Limited Partnership, and Green Dolphin Mary Limited Partnership.

2. The Sauganash Foundation is an Ohio corporation with a principal place of business in New Rochelle, New York.

3. The Rockside Foundation is an Ohio corporation with a principal place of business in New Rochelle, New York.

4. Fairmount Investors, L.L.L.P. is a limited liability limited partnership and has the following partners: Edward C. Smith (resident of Cleveland Heights, Ohio), Sarah Phelps Smith (resident of Cleveland Heights, Ohio), Mary Smith Laurent (resident of Shaker Heights, Ohio), John J.A. Smith (resident of Los Angeles, California), Jean Smith Burgess (resident of New Orleans, Louisiana), Margaret Smith Aeschliman (resident of Baltimore, Maryland), Nathaniel E.C. Smith (resident of Cleveland Heights, Ohio), Katherine M. Smith (resident of Cleveland Heights, Ohio), Sarah A.V. Smith (resident of Cleveland Heights, Ohio), Edward C. Smith Irrevocable Trust, and Frederick A. Smith Dynasty Trust. The Edward C. Smith Irrevocable Trust's trustee is Sarah P. Smith (resident of Cleveland Heights, Ohio) and the Edward C. Smith

Irrevocable Trust's beneficiaries are Mary Smith Laurent (resident of Shaker Heights, Ohio), John J.A. Smith (resident of Los Angeles, California), Jean Smith Burgess (resident of New Orleans, Louisiana), Margaret Smith Aeschliman (resident of Baltimore, Maryland), Nathaniel E.C. Smith (resident of Cleveland Heights, Ohio), Frederick Smith II (resident of Baltimore, Maryland), Katherine M. Smith (resident of Cleveland Heights, Ohio), and Sarah A.V. Smith (resident of Cleveland Heights, Ohio). The Frederick A. Smith Dynasty Trust's trustees are Sarah P. Smith (resident of Cleveland Heights, Ohio) and Edward C. Smith (resident of Cleveland Heights, Ohio) and the Frederick A. Smith Dynasty Trust's beneficiaries are Mary Smith Laurent (resident of Shaker Heights, Ohio), John J.A. Smith (resident of Los Angeles, California), Jean Smith Burgess (resident of New Orleans, Louisiana), Margaret Smith Aeschliman (resident of Baltimore, Maryland), Nathaniel E.C. Smith (resident of Cleveland Heights, Ohio), Frederick Smith II (resident of Baltimore, Maryland), Katherine M. Smith (resident of Cleveland Heights, Ohio), and Sarah A.V. Smith (resident of Cleveland Heights, Ohio).

5. The Eastern Shore-Mentor Limited Partnership is a limited partnership and has the following partners: Ann Smith Seabright (resident of Mentor, Ohio), Thomas W. Seabright (resident of Mentor, Ohio), Elizabeth Seabright Budnik (resident of Bratenahl, Ohio), James Seabright (resident of Willoughby, Ohio), Virginia Seabright (Mentor, Ohio), Clair Seabright Wilson (resident of Hermosa Beach, California), Anne Seabright (resident of Los Angeles, California), Mark Seabright (resident of Los Angeles, California), John Seabright (resident of New York, New York), Katherine Seabright (resident of Brooklyn, New York), Mary Caroline Seabright (resident of New York, New York), and Margaret Seabright (resident of Somerville, Massachusetts).

6. The Green Dolphin Charlies Limited Partnership, Green Dolphin James Limited Partnership, Green Dolphin John Limited Partnership, Green Dolphin Thomas Limited Partnership, Green Dolphin Sarah Limited Partnership, and Green Dolphin Mary Limited Partnership are limited partnerships and collectively referred to as the “Green Dolphin Partnerships.” The Green Dolphin Partnerships have the following partners: Charlies Podles (resident of Baltimore, Maryland), James Podles (resident of Vancouver, B.C., Canada), John Podles (resident of Baltimore Maryland), Thomas Podles (residence of Baltimore, Maryland), Sarah Podles Misra (resident of San Francisco, California), and Mary Podles Mullaj (resident of Baltimore, Maryland).

7. Dr. Thanoo is an individual who, upon information and belief, resides at 4 Margaret Drive, Somerset, New Jersey 08873. Dr. Thanoo was employed by and last served as a Vice President of Product Development for Oakwood and is now employed by Aurobindo USA, a direct competitor of Oakwood.

8. AuroMedics is a Delaware limited liability company with its principal place of business located in Middlesex County, New Jersey. Upon information and belief, the members of AuroMedics are not citizens of the same state as any of Oakwood’s members.

9. Aurobindo USA is a Delaware corporation with its principal place of business located in Mercer County, New Jersey.

10. Aurobindo is an Indian corporation with its principal place of business located in India.

JURISDICTION, VENUE, AND SERVICE OF PROCESS

11. This court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332 because diversity of citizenship exists and the amount in controversy exceeds \$75,000 exclusive of interest and costs.

12. This court also has subject matter jurisdiction over the claims pursuant to the provisions of 28 U.S.C. § 1331 (federal question jurisdiction) as a claim arises under 18 U.S.C. § 1832, *et seq.*, the Defend Trade Secrets Act of 2016.

13. This Court has personal jurisdiction over Dr. Thanoo and Aurobindo USA pursuant to N.J. Ct. R. 4:4-4(a).

14. This Court has personal jurisdiction over Aurobindo and AuroMedics by virtue of paragraph 16 of the Mutual Confidentiality Agreement entered into by Aurobindo, AuroMedics, and Oakwood.

15. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claims occurred in this District.

16. Aurobindo USA and AuroMedics were served with a summons and the original complaint in this action on July 13, 2017 (Docket Nos. 4-5). Dr. Thanoo was served on July 17, 2017 (Docket No. 6). Aurobindo waived service of process on August 29, 2017 (Docket No. 17).

FACTS

A. Oakwood's Confidential Information and Trade Secrets

17. Oakwood is a technology-based specialty pharmaceutical company focused on hard-to-develop generic and quasi-generic, sustained-release, and small molecule injectable drugs, as well as contract manufacturing. This includes the research and development of sustained release injectable drugs involving microsphere systems (collectively, the "Oakwood Products").

18. Oakwood has devoted extensive time, money, and other resources to the research, design, and development of the Oakwood Products it manufactures including, but not limited to, the design, development, and testing of various injectable drugs, the design, development, and testing of microsphere systems technologies, the design and development of various research processes, the design and development of various quality assurance and regulatory compliance processes, the design and development of various manufacturing processes, contractual arrangements with customers, the identities of contact persons with customers and suppliers, batch record formats and content, standard operating procedures, drug master files, freeze dry cycles and development, product development lists, formation development research, validation methods, validation data and reports, and new drug application (“NDA”) filings, planned filings, and associated data.

19. The design, development, and testing processes, the research processes, the quality assurance and compliance processes, and the manufacturing processes for the Oakwood Products are not generally known outside Oakwood’s organization, and Oakwood takes steps reasonable under the circumstances to keep such information confidential, including, but not limited to, having its scientists sign invention and non-disclosure agreements, having potential and actual vendors, suppliers, and other business partners sign confidentiality agreements before sharing information, advising all employees through policy of the requirement that such information must be held confidential, password protecting electronically stored information, and reasonably controlling access to such information. Therefore, such information constitutes trade secrets under NJ Rev Stat § 56:15-2 (2013) and is hereinafter referred to as Oakwood’s “Confidential Information and Trade Secrets.”

20. Oakwood takes such precautions to maintain the secrecy of its Confidential Information and Trade Secrets because Oakwood would suffer irreparable competitive harm if its Confidential Information and Trade Secrets were to be obtained by, or used on behalf of, its competitors and, further, would suffer additional irreparable harm through the loss of its good will if competitors utilized Oakwood's Confidential Information and Trade Secrets to solicit and do business with such customers.

21. Given the highly competitive nature of the microsphere-based sustained release injectable drug industry, the information generated and received by Oakwood's scientists while conducting research and development is vitally important to Oakwood, is deemed by Oakwood to constitute its confidential information, and is known to be such by Oakwood's employees.

22. In addition to having access to confidential information relating to the research and development of Oakwood's microsphere-based sustained release injectable drug products, Oakwood's scientists also have access to confidential information relating to the manufacturing of Oakwood's microsphere-based sustained release injectable drug products and to the confidential business and financial arrangements between Oakwood and third-party laboratories, vendors, and joint venturers that participate in the research, development and manufacturing of the Oakwood's microsphere-based sustained release injectable drug products.

B. Dr. Thanoo's Employment At Oakwood

23. Oakwood hired Dr. Thanoo on or about November 24, 1997, in the position of Senior Scientist. As a condition of employment and to protect Oakwood from misuse and/or disclosure of proprietary information, Oakwood required Dr. Thanoo to sign both an Inventions Agreement ("Inventions Agreement"), a true and accurate copy of which is attached hereto as **Exhibit A** (and incorporated herein by reference), and a Non-Disclosure Statement Agreement

(“Non-Disclosure Agreement”), a true and accurate copy of which is attached hereto as **Exhibit B** (and incorporated herein by reference).

24. Paragraph 2 of Dr. Thanoo’s Invention Agreement provides, in part, as follows:

Employee agrees he will fully and promptly disclose to Oakwood Laboratories, L.L.C., through its President or other duly authorized designee, all invention and improvements, whether then believed or later found to be patentable or not, made or conceived solely by Employee, or jointly with another or other, within the whole term of his employment by Oakwood Laboratories, L.L.C., and for twenty-four months (24) after the termination of such employment, which relates to or are useful in the business, research, investigations, products, machines, and all lawful interests and activities of Oakwood Laboratories, L. L. C. Employee further agrees that he will always upon Oakwood Laboratories, L.L.C. 's request or demand, promptly perform all proper and necessary legal acts to assign to and vest in Oakwood Laboratories, L.L.C., the entire right, title and interest in and to all such inventions and/or improvements and all Letters Patent, United States and foreign therefor, together with the entire and exclusive rights to seek, obtain and enjoy all such Letters Patent. To that end Employee agrees that he will at all times execute and deliver to and/or adduce or give in behalf of Oakwood Laboratories, L.L.C., promptly at its request any lawful writings, assignments, application papers, powers, oaths, evidence and testimony to vest, protect and secure in Oakwood Laboratories, L.L.C. all the rights, titles, and interest in inventions improvements, applications, and patents to which this agreement pertains. Employee further agrees to comply with the practice and rules from time to time prescribed by Oakwood Laboratories, L.L.C., concerning the making, preserving and possession of written records, drawings, and disclosures of inventions and improvements and otherwise concerning the performance of this agreement, and agrees to respect and preserve all secret and/or confidential information concerning the affairs of Oakwood Laboratories, L.L.C., of which he may become possessed. (Emphasis added.)

25. The Non-Disclosure Agreement prohibits Dr. Thanoo from disclosing or using at any time Oakwood’s Confidential Information and Trade Secrets. The Non-Disclosure Agreement provides, in part:

I understand and acknowledge my obligation to refrain from disclosing Oakwood Laboratories’ confidential and proprietary information and to refrain from using it for the benefits of any other person or entity without the permission of Oakwood Laboratories. I understand that my obligation results from the nature of my employment and the circumstances of disclosure, and will remain even after termination of my employment relationship. (Emphasis added.)

26. The Non-Disclosure Agreement is reasonable in that it does not restrict Dr. Thanoo from working for a competitor of Oakwood. Rather, the restriction only prevents Dr. Thanoo from disclosing or using Oakwood's confidential and proprietary information. The Non-Disclosure Agreement protects a legitimate business interest by protecting proprietary information that is confidential and/or trade secret. The Non-Disclosure Agreement is reasonably necessary for the protection of the business and goodwill developed by Oakwood and Oakwood would sustain irreparable harm if Dr. Thanoo should continue to violate the covenants set forth therein.

27. The trade secrets of Oakwood which Dr. Thanoo acquired during his employment with Oakwood include, but are not limited to, Oakwood's product formulations, product designs and ingredients, manufacturing process, testing procedures and protocols, quality control procedures, and process design controls, including, without limitation, the information set forth in detail at paragraphs 28 and 29 below.

28. During his employment by Oakwood, Dr. Thanoo had extensive involvement in and knowledge of the design, development, and implementation of the Oakwood Products. In his role as Vice President of Product Development and his prior position as Senior Scientist, Dr. Thanoo was principally responsible for the development of the Oakwood Products, including designing or directly supervising the design of Oakwood's microsphere systems technology as well as other injectable drug delivery systems, and coordinating the research, development and testing of the Oakwood Products. Dr. Thanoo directly designed Oakwood's microsphere process technology, and the design, research and development, and test methods for leuprolide¹ and

¹ Leuprolide is a member of the group of drugs known as gonadotropin-releasing hormone analogs (GnRH analogs), also known as luteinizing hormone releasing hormone agonists (LHRH agonists) or LHRH analogs. Leuprolide is a synthetic peptide drug modeled after the human hypothalamic gonadotropin releasing hormone (GnRH). A GnRH analogue is designed to interact with the GnRH receptor and modify the release of pituitary gonadotropins FSH and LH for therapeutic purposes, stopping the release of testosterone from the testicles in men and the release of estrogen

octreotide sustained released products, and other products, that rely on microsphere process technology (referred to herein as the “Microsphere Project”) that Oakwood began developing while Dr. Thanoo was its employee.

29. The Microsphere Project that Dr. Thanoo directed—and is now misappropriating for Defendants’ benefit—required Oakwood to design formulations based on a number of variables which were finally determined after extensive trial and error testing, including, but not limited to, the following:

- a. **Type of polymer selected, including ratio of lactide to glycolide, and type of end group used.** Oakwood internally tested numerous types of polymers in order to select the specific ones that resulted in time release durations of both one and three months. The release of the Active Pharmaceutical Ingredient (“API”) incorporated into the polymer is highly dependent on the interaction of the polymer with the specific API used. This information is not generally known and is the result of long term research and development activities led, in pertinent part, by Dr. Thanoo during his employment with Oakwood. On August 17, 2018, pursuant to the Court’s temporary sealing Order [D.I. 54], Oakwood previously provided to Defendants, as Sealed Exhibit 1 to the Second Amended Complaint (which exhibit is incorporated herein by reference), a chart describing the specific type of polymer selected, including the ratio of lactide to glycolide, and type of end group used, for each of the Leuprolide 1-month release, Leuprolide 3-month release, Octreotide 1-month release, and Risperidone 2-week release developed as a result of Oakwood’s extensive research and development in the Microsphere Project directed by Dr. Thanoo. By Order dated September 26, 2018, the Court permanently sealed this information [D.I. 60]. As such, this information is not reattached hereto as it is already in Defendants’ possession and the Court can take judicial notice of the previously-filed exhibits on its docket. This information and data specifically identifies and enumerates Oakwood’s Confidential Information and Trade Secrets at issue in this case.
- b. **Molecular weight and inherent viscosity of the polymer.** In addition to the type of polymer selected, the molecular weight and inherent viscosity of the selected polymer affects the release profile of the API. Molecular weight is directly correlated to inherent viscosity, and inherent viscosity is used as a measure of molecular weight. Regulatory authorities require specifica-

from the ovaries in women. This reduction of hormone levels slows or stops the growth of cancer cells that depend on these hormones.

tions to be set for inherent viscosity based upon test results. Oakwood conducted extensive experiments, including testing in approximately 180 patients, using three lots of microsphere products manufactured with a range of polymer inherent viscosities in order to determine the appropriate specification. This information is not generally known and is the result of experimentation conducted by Oakwood. On August 17, 2018, pursuant to the Court's temporary sealing Order [D.I. 54], Oakwood previously provided to Defendants, as Sealed Exhibit 2 to the Second Amended Complaint (which exhibit is incorporated herein by reference), a chart describing the specific inherent viscosity ranges of each of the polymers used for the Leuprolide 1-month release, Leuprolide 3-month release, Octreotide 1-month release, and Risperidone 2-week release developed as a result of Oakwood's extensive research and development in the Microsphere Project directed by Dr. Thanoo. By Order dated September 26, 2018, the Court permanently sealed this information [D.I. 60]. As such, this information is not reattached hereto as it is already in Defendants' possession and the Court can take judicial notice of the previously-filed exhibits on its docket. This information and data specifically identifies and enumerates Oakwood's Confidential Information and Trade Secrets at issue in this case.

- c. **Ratio of drug to polymer, both targeted and achieved.** The ratio of drug to polymer affects the release profile of the drug from the microspheres. In general, a higher drug load results in a faster release profile, but this is also highly dependent upon the specific API used and its interaction with the polymer. The only way to determine the appropriate drug load in order to obtain the desired release profile is by experimentation, which was conducted by Oakwood. On August 17, 2018, pursuant to the Court's temporary sealing Order [D.I. 54], Oakwood previously provided to Defendants, as Sealed Exhibit 3 to the Second Amended Complaint (which exhibit is incorporated herein by reference), a chart describing the specific drug load for each of the Leuprolide 1-month release, Leuprolide 3-month release, Octreotide 1-month release, and Risperidone 2-week release developed as a result of Oakwood's extensive research and development in the Microsphere Project directed by Dr. Thanoo. By Order dated September 26, 2018, the Court permanently sealed this information [D.I. 60]. As such, this information is not reattached hereto as it is already in Defendants' possession and the Court can take judicial notice of the previously-filed exhibits on its docket. This information and data specifically identifies and enumerates Oakwood's Confidential Information and Trade Secrets at issue in this case.
- d. **Type of process used to form microspheres.** There are several different approaches to forming microsphere products, each resulting in different release profiles of the products produced. This information is not generally known and Oakwood conducted extensive experimentation to arrive at the process it uses for the Microsphere Project and other Oakwood Products. On August 17, 2018, pursuant to the Court's temporary sealing Order [D.I. 54], Oakwood previously provided to Defendants, as Sealed Exhibit 4 to the

Second Amended Complaint (which exhibit is incorporated herein by reference), a schematic describing the specific microsphere manufacturing process developed as a result of Oakwood's extensive research and development in the Microsphere Project directed by Dr. Thanoo. Importantly, Oakwood's microsphere manufacturing process is distinguished by the configuration of the input to the modified Silverson homogenizer. This distinguishing feature of Oakwood's microsphere manufacturing process was developed as a result of Oakwood's extensive research and development in the Microsphere Project directed by Dr. Thanoo. By Order dated September 26, 2018, the Court permanently sealed this information [D.I. 60]. As such, this information is not reattached hereto as it is already in Defendants' possession and the Court can take judicial notice of the previously-filed exhibits on its docket. This information and data specifically identifies and enumerates Oakwood's Confidential Information and Trade Secrets at issue in this case.

- e. **Mixing speeds used in the process.** The mixing speeds used in the process affects the particle size, drug incorporation, and other factors that affect the release of the drug from the microspheres. In order to obtain a process that is well controlled, regulatory authorities require extensive experimentation to demonstrate a range of process parameters that result in a consistent product. This information is not generally known and is the result of experimentation conducted by Oakwood. On August 17, 2018, pursuant to the Court's temporary sealing Order [D.I. 54], Oakwood previously provided to Defendants, as Sealed Exhibit 5 to the Second Amended Complaint (which exhibit is incorporated herein by reference), a chart describing the specific homogenizer mixing speed for microsphere formation used for each of the Leuprolide 1-month release, Leuprolide 3-month release, Octreotide 1-month release, and Risperidone 2-week release developed as a result of Oakwood's extensive research and development in the Microsphere Project directed by Dr. Thanoo. By Order dated September 26, 2018, the Court permanently sealed this information [D.I. 60]. As such, this information is not reattached hereto as it is already in Defendants' possession and the Court can take judicial notice of the previously-filed exhibits on its docket. This information and data specifically identifies and enumerates Oakwood's Confidential Information and Trade Secrets at issue in this case.
- f. **Types and quantities of solvents used in the process.** There are numerous types of solvents that can be used in manufacturing microsphere-based products. The type, and rate of extraction, of the solvents used affects the porosity of the microspheres and, thus, the release of the API from the polymer matrix of the microsphere. The selection of appropriate solvent(s) is not generally known and is the result of experimentation conducted by Oakwood. On August 17, 2018, pursuant to the Court's temporary sealing Order [D.I. 54], Oakwood previously provided to Defendants, as Sealed Exhibit 6 to the Second Amended Complaint (which exhibit is incorporated herein by reference), a chart describing the specific types and quantities of

solvents used in the microsphere formation process for each of the Leuprolide 1-month release, Leuprolide 3-month release, Octreotide 1-month release, and Risperidone 2-week release developed as a result of Oakwood's extensive research and development in the Microsphere Project directed by Dr. Thanoo. By Order dated September 26, 2018, the Court permanently sealed this information [D.I. 60]. As such, this information is not reattached hereto as it is already in Defendants' possession and the Court can take judicial notice of the previously-filed exhibits on its docket. This information and data specifically identifies and enumerates Oakwood's Confidential Information and Trade Secrets at issue in this case.

- g. **Flow rates used in the process.** The flow rates of liquids used to form microspheres impacts the morphology of the microsphere which, in turn, affects the release profile. Regulatory authorities require extensive experimentation to demonstrate a range of process parameters, including flow rates, that result in a consistent product. This information is not generally known and is the result of experimentation conducted by Oakwood. On August 17, 2018, pursuant to the Court's temporary sealing Order [D.I. 54], Oakwood previously provided to Defendants, as Sealed Exhibit 7 to the Second Amended Complaint (which exhibit is incorporated herein by reference), a chart describing the specific flow rates used in the microsphere formation process for each of the Leuprolide 1-month release, Leuprolide 3-month release, Octreotide 1-month release, and Risperidone 2-week release developed as a result of Oakwood's extensive research and development in the Microsphere Project directed by Dr. Thanoo. By Order dated September 26, 2018, the Court permanently sealed this information [D.I. 60]. As such, this information is not reattached hereto as it is already in Defendants' possession and the Court can take judicial notice of the previously-filed exhibits on its docket. This information and data specifically identifies and enumerates Oakwood's Confidential Information and Trade Secrets at issue in this case.
- h. **Processing times and holding times for various solutions and suspensions of microspheres.** Similar to mixing speeds and flow rates, processing times are critical process parameters that must be controlled. The specific holding times can only be determined by experimentation and are not generally known. In the process of scaling up from prototype batches to commercial scale, modifications to the process were required which involved extensive experimentation by Oakwood. On August 17, 2018, pursuant to the Court's temporary sealing Order [D.I. 54], Oakwood previously provided to Defendants, as Sealed Exhibit 8 to the Second Amended Complaint (which exhibit is incorporated herein by reference), a chart describing the specific processing and hold times and temperatures used in the microsphere formation process for each of the Leuprolide 1-month release, Leuprolide 3-month release, Octreotide 1-month release, and Risperidone 2-week release developed as a result of Oakwood's extensive research and development in the Microsphere Project directed by Dr. Thanoo. By Order

dated September 26, 2018, the Court permanently sealed this information [D.I. 60]. As such, this information is not reattached hereto as it is already in Defendants' possession and the Court can take judicial notice of the previously-filed exhibits on its docket. This information and data specifically identifies and enumerates Oakwood's Confidential Information and Trade Secrets at issue in this case.

30. The Court has held that the Confidential Information and Trade Secrets, set forth in paragraph 29a-h above, have been adequately pleaded by Oakwood as trade secrets under applicable law. *See* Memorandum and Order [D.I. 67] at 5 ("Plaintiff has identified trade secrets[.]").

31. As discussed below, Dr. Thanoo knew, possessed or had access to all of this information and data when he went to work for Aurobindo. None of this information was generally known and was the result of long-term research and development activities occurring over a period of years by Oakwood, led by Dr. Thanoo while employed by Oakwood.

32. As a result of his employment with Oakwood, Dr. Thanoo acquired extensive and thorough knowledge of the designs, processes, and ingredients described above. Each of these factors described above (including those in Paragraphs 28 and 29) interact with the other, and each can dramatically affect the release profile of the product and are proprietary to Oakwood. As a result, the development of a product with the correct release profile requires extensive experimentation, including the manufacture and testing of hundreds of trial batches, using multiple variations of the above factors. The testing involved is also highly time consuming, because the formulations release the drug over extended periods of time. To test the release profile of a three-month duration product in real time requires in excess of three months. These tests are performed with *in vitro* test methods, in animals, and in humans. Often a formulation that appears promising based upon *in vitro* test methods will fail in animal and human testing, and the product must be reformulated. Oakwood has spent roughly 20 years developing bio-equivalent microsphere-based

versions of leuprolide and octreotide peptides and Dr. Thanoo was involved in, and later directed, these developments. As a result, Dr. Thanoo has extensive knowledge of Oakwood's testing results and the design of its formula for the Microsphere Project as well as the other Oakwood Products.

33. Oakwood has spent approximately 20 years developing, refining, and perfecting the Microsphere Project.

34. Oakwood estimates that it has invested more than \$130 million into the Microsphere Project during that time.

35. Oakwood estimates that it has dedicated the full-time man-hours of 20-40 employees into the Microsphere Project during that time.

36. Specifically with respect to Dr. Thanoo, he spent more than 80% of his tenure with Oakwood working on the Microsphere Project.

37. Thus, the Microsphere Project is not something that could have been replicated in one-to-four years (as discussed below) absent misappropriation of Oakwood's trade secrets.

38. The detailed confidential information related to the research and development of Oakwood's microsphere-based sustained release injectable drug products as well as to Oakwood's manufacturing, business and financial information to which Dr. Thanoo had access while employed as Vice President of Product Development of Oakwood was neither generally known to, nor ascertainable by, third parties.

39. Given the competitive nature of the microsphere-based sustained release injectable drug industry, that confidential information derived its independent economic value from not being generally known to and not being readily ascertainable through proper means by other persons who could obtain economic value from its disclosure or use.

40. Oakwood employed reasonable efforts to maintain the secrecy of its confidential research and development, manufacturing, business and financial information.

C. Oakwood Discusses A Business Venture With Aurobindo

41. Aurobindo, headquartered in Hyderabad, India, manufactures generic pharmaceutical drugs and active pharmaceutical ingredients (“API”) related primarily to seven major therapeutic and product areas that encompass neurosciences, cardiovasculars, gastroenterologicals, antibiotics, anti-retrovirals, anti-diabetics and anti-allergics. Aurobindo operates in 150 different countries, including the United States through its subsidiary Aurobindo USA, which is based in New Jersey.

42. On October 3, 2013, V. Ganesh Ramnan (“Mr. Ramnan”), General Manager of Sales and Marketing at Aurobindo USA, met with Oakwood’s Chief Executive Officer, Mark Smith (“Mr. Smith”), and Dr. Thanoo at Oakwood’s headquarters in Cleveland, Ohio, to discuss Oakwood’s peptides product and a potential collaborative working relationship in connection with peptide products.

43. It was Aurobindo that sought out Oakwood for this potential collaborative working relationship.

44. In subsequent emails with Mr. Ramnan, Mr. Smith discussed a business venture in which Aurobindo USA would sell an API to Oakwood for its Microsphere Project.

45. In an email on November 13, 2013, Mr. Smith noted:

Oakwood has developed and has just started to pursue a collaboration for three of its leading product candidates which are three/four month sustained release leuprolide injections of differing doses. All three products are bioequivalent to comparable dosage forms of Abbott Laboratories’ Lupron Depot®, and can be approved on the basis of one bioequivalence trial. There currently are no approved generic versions of these products in the US due to the high level of difficulty in developing and manufacturing such specialized products. Attached please find a brief summary of this opportunity.

Mr. Smith concluded the email by noting that he would like to discuss the leuprolide products further, on the condition that Aurobindo enter into a confidentiality agreement.

46. On November 18, 2013, Aurobindo Chief Executive Officer N. Govindarajan (“Mr. Govindarajan”) visited Oakwood’s headquarters where he met with Mr. Smith to discuss Aurobindo’s and Aurobindo USA’s capabilities. Mr. Govindarajan also spoke with Dr. Thanoo during his visit to Oakwood.

47. During these discussions, Aurobindo informed Oakwood that it had no prior experience with peptide based microsphere products.

48. On November 20, 2013, Mr. Govindarajan connected via email Dr. Thanoo and J.V.N. Reddy (“Dr. Reddy”), Vice President of Aurobindo, noting that the two were old friends and “batch mate[s] at Madras University.”

49. On November 29, 2013, Aurobindo executed a confidentiality agreement between it, AuroMedics, another U.S. subsidiary of Aurobindo based in New Jersey, and Oakwood, wherein each of the parties agreed to not disclose or use any confidential information shared by the other parties while discussing the Microsphere Project and the leuprolide products (the “Confidentiality Agreement”). (A true and accurate copy of the Mutual Confidentiality Agreement is attached hereto as **Exhibit C** (and incorporated herein by reference)). AuroMedics subsequently executed the confidentiality agreement on December 2, 2013, and Oakwood on December 3, 2013.

50. On December 3, 2013, Oakwood sent the fully executed confidentiality agreement to Aurobindo and AuroMedics along with confidential information including a 27-page memorandum explaining the leuprolide products (the “Leuprolide Memo”).

51. The Leuprolide Memo contained numerous Oakwood trade secrets regarding the Microsphere Project, including Oakwood's development of the microsphere-based leuprolide products, including the specific ingredients of the formula used to develop the three/four month sustained release leuprolide injections (the "Leuprolide Products"), Oakwood's strategic plan to obtain regulatory approval of the Leuprolide Products, the results of its clinical trials of the Leuprolide Products and the alterations Oakwood made to the formula following its analysis of the clinical trial results, Oakwood's strategy to continue to refine the Leuprolide Products formula, the forecasted costs associated with launching the Leuprolide Products, and the manufacturing process for the Leuprolide Products.

52. Pursuant to the Confidentiality Agreement, Aurobindo and AuroMedics agreed to "use the Confidential Information of a Disclosing Party **solely for the Permitted Use** and for no other purpose. Recipient will keep all Confidential Information of a Disclosing Party secret and confidential and will not reproduce, distribute, disclose, make available or otherwise disseminate Confirmation Information..." (Exhibit C, ¶ 3) (emphasis added).

D. Aurobindo's Lures Dr. Thanoo

53. On December 16, 2013, representatives from Oakwood, including Dr. Thanoo, Aurobindo and AuroMedics engaged in a conference call to discuss the Microsphere Project and the Leuprolide Products.

54. On December 17, 2013, Mr. Ramnan sent an email to Dr. Thanoo noting that he tried to call Dr. Thanoo and wanted to know when Dr. Thanoo might be available to talk. Mr. Ramnan did not mention the subject of the discussion. Dr. Thanoo responded that he was out of the country on a work-related trip and would be available to talk later in the week. Mr. Ramnan

tried to call Dr. Thanoo again on December 20, 2013, and followed the missed call with an email that included his cell phone number so that Dr. Thanoo could call back.

55. On January 9, 2014, Dr. Reddy sent his username for Skype, an Internet-based video conferencing system, to Dr. Thanoo so that the two could speak via video later that day.

56. Ultimately, Aurobindo informed Oakwood that it was not interested in pursuing the Microsphere Project and the Leuprolide Products with Oakwood due to financial considerations.

57. Despite having materially explored a business relationship with Oakwood, Aurobindo instead recruited and hired Dr. Thanoo, thus terminating the need for a business relationship among the companies.

58. Oakwood subsequently engaged a different company to provide API for the Leuprolide Products developed in connection with the Microsphere Project, which it continues to develop for the market.

E. Dr. Thanoo Leaves Oakwood For Aurobindo To Develop A Product Substantially Similar To Oakwood's Microsphere Project

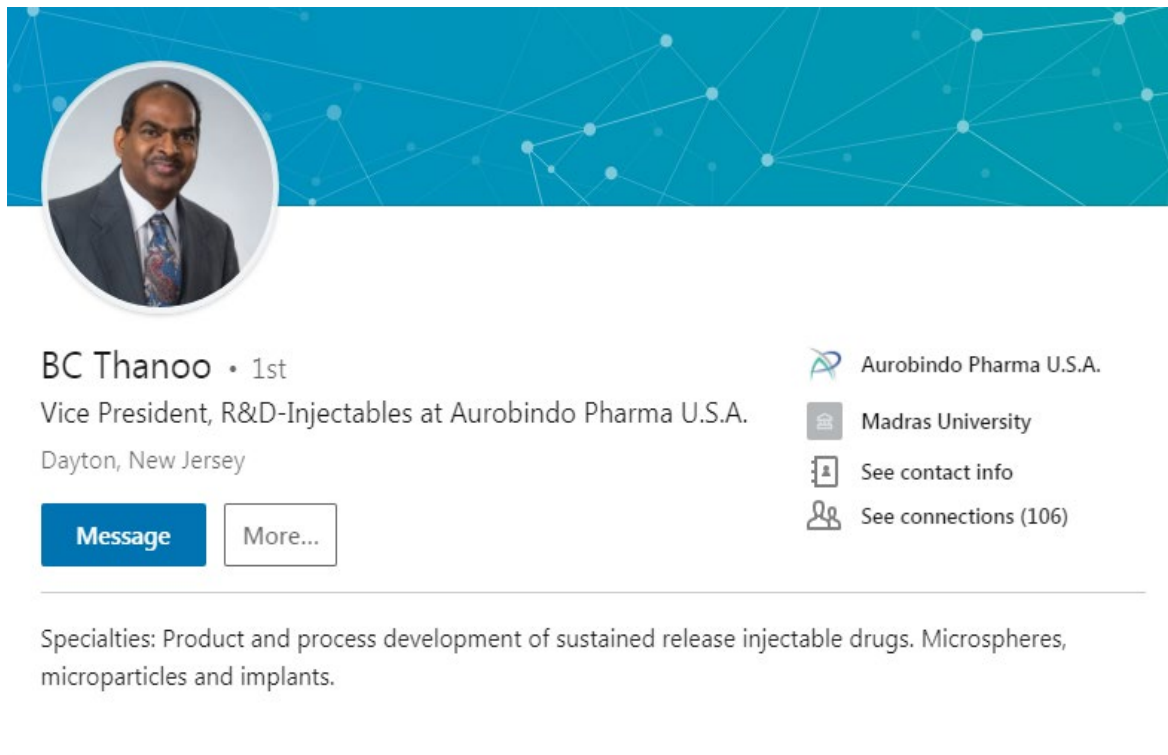
59. On April 7, 2014, Dr. Thanoo tendered his resignation from Oakwood and informed Oakwood that it was effective April 25, 2014. During a follow-up conversation, Dr. Thanoo told Mr. Smith that he was going to Aurobindo USA to develop standard generic injectable drugs. Dr. Thanoo expressly stated that his work at Aurobindo USA would not include microsphere system technology. Contrary to his prior and false assertions to Oakwood, Dr. Thanoo routinely and regularly worked on products involving microsphere system technology while employed by Aurobindo USA.

60. During the period of 2013, Dr. Thanoo instructed subordinates to send to his personal email address Oakwood's trade secret information regarding the Oakwood Products,

including trade secret information related to the testing and processing of Oakwood's microsphere systems technologies involving leuprolide and octreotide.

61. In April 2014, Aurobindo USA hired Dr. Thanoo in the position of Vice President of R&D Injectables, with a focus on development of "complex generic injectable drugs." Dr. Thanoo is engaging in work that includes microsphere process technology and the same sustained release versions of leuprolide, octreotide, and possibly other products developed at Oakwood. Of course, when he did so, Dr. Thanoo and Aurobindo had the benefit of Oakwood's proprietary and confidential trade secret information and data.

62. Dr. Thanoo's LinkedIn page, which is excerpted below and attached hereto as **Exhibit D** (and incorporated herein by reference), confirms that he is engaged in the same type of work, research and/or development for Aurobindo, Aurobindo USA, and AuroMedics that he worked on for over 16 years at Oakwood:



Experience



Vice President, R&D-Injectables

Aurobindo Pharma U.S.A.

Apr 2014 – Present · 4 yrs 11 mos

Dayton, New Jersey

Development of complex generic injectable drugs.



Vice President, Product Development

Oakwood Laboratories

1998 – Apr 2014 · 16 yrs

Cleveland/Akron, Ohio Area

Development of sustained release injectables.

Design, develop, and manufacturing of microparticles, microspheres, nanoparticles for controlled release of pharmaceutical agents.

See Exhibit D; <https://www.linkedin.com/in/bc-thanoo-52b8b513> (last visited March 11, 2019).

63. Dr. Thanoo exercises control over the content of (and representations contained in) his own LinkedIn page.

64. Within months after Dr. Thanoo began working for Aurobindo USA, Aurobindo announced during a February 5, 2015 investor call, which is excerpted below in pertinent part and attached hereto in full as **Exhibit E** (and incorporated herein by reference), that it had microsphere-based products in development and was one of only a limited number of companies in the highly-specialized microsphere space:

N. Govindarajan: As far as Penem is concerned, I will allow Ron to answer and even on Peptides like Ron is running certain finished products including the microsphere as he was explaining, so he can give clarity on both front before I get into the Peptide bulk aspect of it.

Ronald Quadrel: On the Penem side, the addressable market for all four products is \$400 million in the US. As there are already some competitors in there, so obviously we would not be the first in. We hopefully will be in the first group of companies of approved for ertapenem which is the biggest of those. The current market for Ertapenem is well over \$200 million and that is scheduled to come off patent in 2017. From the perspective of Nanospheres it is a much larger market right now, where the products we are looking at the addressable market currently is about \$3 billion in the US. We are assuming that there will be 3 or 4 other

competitors in that market. Our opportunity in this particular market would be dependent upon when we are approved versus other competitors. Given that we are starting this year, most likely on several of our products we would not be the first out, but on the latter products probably we would be in the first group.

Exhibit E at 19.

65. Shortly thereafter, AuroMedics formed a group in the United States to develop microsphere technology. Aurobindo announced this during a May 29, 2015 investor call, which is excerpted below in pertinent part and attached hereto as **Exhibit F** (and incorporated herein by reference):

N. Govindarajan: I believe it should be peptide, sir as far as peptide is concerned our first DMF is going to be filed by this quarter, by the end of this quarter, the second product would be by next quarter. So we expect every quarter one product to be filed as we continue in terms of the API level, the DMF. What is more significant which Ron can throw more light is like apart from forward integrating in terms of microsphere and Ron you can throw some light in terms of the microsphere products?

Ronald Quadrel: Sure. This past year we formed a group in the US here, specifically to develop some microsphere and liposomal injectable 1 products. This year by the end of this fiscal year we will have invested about \$6 million in to the four projects that we are currently working on. The addressable market of those four products is about \$3 billion. We are expecting that we will start filing these products probably end of calendar 2016 beginning 2017 because there are some lengthy BE studies that have to be conducted and also physical chemical characterization studies. I am expecting that our first approval will probably be sometime in calendar year 2018 with the first product followed closely by the other three products.

N. Govindarajan: But what is more important is sir these products would have limited competition unlike the typical products.

Rakesh Jhunjunwala: And they are on the peptide area?

N. Govindarajan: Yes sir. This is on the microsphere which is a forward integration of the peptide.

Exhibit F at p. 16.

66. Aurobindo, Aurobindo USA, and AuroMedics had no prior experience researching microsphere technology before hiring Dr. Thanoo.

67. Aurobindo, Aurobindo USA, and AuroMedics had no prior experience developing microsphere technology before hiring Dr. Thanoo.

68. Aurobindo, Aurobindo USA, and AuroMedics had no prior experience manufacturing microsphere technology before hiring Dr. Thanoo.

69. Aurobindo, Aurobindo USA, and AuroMedics had no prior experience selling microsphere technology before hiring Dr. Thanoo.

70. By the time of an August 14, 2015 investor call, which is excerpted below in pertinent part and attached hereto as **Exhibit G** (and incorporated herein by reference), AuroMedics had already built a team around Dr. Thanoo and was capitalizing on his microsphere experience gained at Oakwood on the peptide area:

Manoj Garg: Another question basically if you look at three or five years down the line, obviously you are taking a lot of initiatives in terms of Microsphere technology, Peptide-based kind of products. How do you see Aurobindo's pipeline evolving over the next 5-years?

N. Govindarajan: We clearly believe that it would be highly differentiated compared to where we stand, Manoj. In terms of filing, it is easy to predict, in terms of approval, it is difficult to predict. As you talked about Microsphere technology, we had mentioned in the earlier call as well we are planning to file our first product by around 2017. Ron had also mentioned around four products having a market size of around 3 billion. So instead of looking at quantitatively in terms of the number of products, qualitatively I think even one or two product approvals can clearly change the shape of what we look at in terms of the differentiation. So, clearly, we see that the degree of differentiation would be much better than where we stand today. So, are we putting any specifics? It is very difficult at this juncture, Manoj.

....

Nishit Shah: But my question was on Nanosphere which is where the \$3 billion market is. How will that take post the approval of the plant by the FDA and when that market opportunity opening up for Auro?

Ronald Quadrel: What I can tell you is as I mentioned this earlier obviously, Nanosphere's liposomes and microsphere specifically are much-much harder to develop than straight liquids of suspensions. Also, every single product requires a bioequivalence study plus some additional chemistry testing which we call a physical chemical characterization. That whole program takes probably an extra year and a half more than a normal development time. So, as Govind answered

earlier, we are expecting the first filing to be in 2017 and the others will follow shortly behind that. I would expect especially with PDUFA now in place, that we should have approvals, if the FDA keeps its current timing or even approves a little bit, within around 24- months or so after we file. So, we are still a ways off yet, but very encouraging. *Not every company can do these, but we have some very good experts working on these development projects and we are making significant progress.*

Exhibit G at 9, 17 (emphasis added).

71. In the investor calls that followed, Aurobindo continually represented that it was making progress bringing its microsphere technology to market.

- a. See, e.g., November 9, 2015 investor call at 3 (attached hereto as **Exhibit H** and incorporated herein by reference) (“We have several products under development, namely Hormonal and Oncology products including Microsphere which we plan to file over the next 18 to 24-months.”);
- b. February 10, 2016 investor call at 8 (attached hereto as **Exhibit I** and incorporated herein by reference) (“I believe we will file our first Microsphere product about 4-5-quarters out from now. One of the reasons is taking longer to do that is, it is a much more complex development, and as well, we require some initial pilot bioequivalent studies followed by full bioequivalence. It will take that much time to get to that point, but so far everything looks good.”);
- c. *Id.* at 21 (“In terms of the Depot Injections which are the Liposomal and the Microspheres products I had mentioned earlier, I am expecting that we will be filing at least three of our four products in 2017. So things are progressing very well on that front.”); and
- d. May 31, 2016 investor call at 3 (attached hereto as **Exhibit J** and incorporated herein by reference) (“We have several complex products

under development, namely Hormones, Oncology and Microsphere which we plan to start filing over the next four-to-six quarters.”).

72. The group that AuroMedics formed was clearly busy using Dr. Thanoo to misappropriate Oakwood’s trade secrets, because by the time of an August 24, 2016 investor call, Aurobindo announced that it was already developing “four Peptide based Microsphere product[s] which [have] around a \$3 billion top-line[.]” The full transcript of the August 24, 2016 investor call is attached as **Exhibit K** (and incorporated herein by reference).

73. This is significant because Aurobindo had not developed microsphere products prior to the hiring of Dr. Thanoo. Those four peptide-based microsphere products referenced in the August 24, 2016 investor call include products with leuprolide and octreotide peptides. These two products, and possibly others, were part of Oakwood’s Microsphere Project.

74. The August 24, 2016 investor presentation is confirmed by Aurobindo’s 2016-2017 Annual Report, which is attached hereto as **Exhibit L** (and incorporated herein by reference). That report confirms that Aurobindo “has forayed” into “specialty injection products” and expects “exhibit batches” to be produced “starting in the first quarter of 2018.” *See* Exhibit L at p. 14.

75. Aurobindo’s “foray” into specialty injection products included hiring Thanoo in order to misappropriate Oakwood’s trade secrets.

76. Further, Aurobindo’s May 2017 investor presentation (attached as **Exhibit M** (and incorporated herein by reference)) confirmed that these “microsphere technology based specialty injection projects” are being developed in the very same Dayton, New Jersey R&D center where Dr. Thanoo works. *See* Exhibit M at p. 14.

77. The 2017 investor calls confirm that Aurobindo is close to bringing its misappropriated microsphere technology to market.

- a. *See, e.g.*, February 10, 2017 investor call at 3 (attached hereto as **Exhibit N** and incorporated herein by reference) (“AuroMedics, the injectable business maintained its growth momentum during the quarter with sales at \$ 42.5 million, posting a growth of 91% year-on-year. We launched three new products during the quarter, taking the total launches to 10 during the first nine months of this year. Under the Injectable segment, including Ophthalmics, we have filed a total of 89 products as on December 31, 2016 out of which 50 have received approval, including two tentative approvals, and the balance are awaiting approvals. We received two approvals during the quarter. We have a large number of complex products under development namely Hormones, Oncology, Inhalation, Topical, Liposomal and Microsphere based depot injections which we plan to start filing over the next three to six quarters.”);
- b. May 30, 2017 investor call at 8 (attached hereto as **Exhibit O** and incorporated herein by reference) (“**Nishit Shah**: If you can give some color on the progress on the Microsphere side, and then on Dermatology and Inhaler side? **P.V. Ramaprasad Reddy**: We do not want to tell about the specific products. But we are sure we will file at least three products. Our plan is to file before end ’17-18 or early ’18-19.”);
- c. August 10, 2017 investor call at 15 (attached hereto as **Exhibit P** and incorporated herein by reference) (“**Nishit Shah**: You expand to do the clinical trials for the microspheres this year. When do you expect that to

start? **N. Govindarajan:** We have said clinical trials next year, and it will go as scheduled.”); and

- d. November 10, 2017 investor call at 20 (attached hereto as **Exhibit Q** and incorporated herein by reference) (“**Nishit Shah:** Most of my questions are answered, except in that on Biosimilars, can you give me a flavor if you were to file 1 product, so is the clinical trial started on that product? I'm talking about the microsphere, sorry. **Narayanan Govindarajan:** Next financial year, we would be filing.”).

78. In fact, as of March 7, 2019, Defendants are actively soliciting scientists to work under Dr. Thanoo on “sustained release injectable formulations”:

iJOBS-related news:

Job for fresh PhD at Aurobindo Pharma

Aurobindo Pharma in Dayton NJ is looking for a fresh, Ph.D. candidate with suitable background (details are shown below). Candidate with US working permit is highly preferred.

MS or PhD in Science or engineering, additional experience is plus

Knowledge in polymers, emulsions and suspensions

Experience in developing sterile suspension products

Experience in process equipment design and knowledge in fluid dynamics

Aseptic manufacturing knowledge and skill

Knowledge in FDA regulations and guidelines for injectable drugs

Knowledge in Quality-by-Design concept and experience in implementing this concept during product development

Need to work in the lab environment on sustained release injectable formulations. Product has to be developed at lab scale initially and should be able to scale up to commercial batch size. Need to write SOPs, protocols, batch sheets and technical reports.

B.C. Thanoo, Ph.D

Vice President, R&D Injectables

bthanoo@aurobindousa.com

See **Exhibit R** hereto (which is incorporated herein by reference).

79. The objectives of Defendants’ misappropriation of Oakwood’s trade secrets have already or inevitably will come to fruition. Specifically, in a February 8, 2018 investor call, Aurobindo announced that its first “filing” with respect to microsphere products “can happen by

end of FY'19 or beginning of FY'20." The full transcript of the February 8, 2018 investor call is attached as **Exhibit S** (and incorporated herein by reference).

80. A concise timeline crystallizes that Defendants have misappropriated Oakwood's trade secrets and are liable to Oakwood for monetary damages:

Date	Event
October 3, 2013	Aurobindo USA's General Manager of Sales and Marketing approaches Oakwood to discuss collaboration on a peptide project
November 18, 2013	Aurobindo's CEO meets with Dr. Thanoo
November 20, 2013	Aurobindo's CEO emails Dr. Thanoo
November 29, 2013	Aurobindo and AuroMedics sign a confidentiality agreement with Oakwood
December 3, 2013	Oakwood sends the Leuprolide Memo
December 16, 2013	Dr. Thanoo participates in a conference call with Aurobindo and Auromedics regarding the Microsphere Project and the Leuprolide Products
April 7, 2014	Dr. Thanoo resigns from Oakwood and joins Aurobindo USA that same month
Between April and December 2014	Auromedics forms a microsphere technology group
May 29, 2015	Aurobindo announces four microsphere projects
August 24, 2016	Aurobindo announces that the four microsphere projects will top \$3 billion
February 8, 2018	Aurobindo announces that the first of the four microsphere projects will soon be filed

81. Defendants have misappropriated Oakwood's trade secrets. It would be implausible for Aurobindo, AuroMedics, and Aurobindo USA to have developed the microsphere products in one-to-four years lacking Oakwood's trade secret information, when it has taken Oakwood nearly 20 years, \$130 million, and countless man-hours of 20-40 full-time employees to do the same.

82. Defendants are developing or have developed a product substantially similar to and competitive with Oakwood's Microsphere Project using Oakwood's trade secret information,

including trade secret information related to the Microsphere Project, which Defendants misappropriated from Oakwood.

83. Defendants could not develop this product within the rapid timeframe set forth above without Dr. Thanoo's assistance and his use of Oakwood's Confidential Information and Trade Secrets, in particular its trade secret information related to the Microsphere Project, in violation of his Non-Disclosure Agreement.

84. Further, Defendants could not develop this product without Oakwood's trade secret information contained in the Leuprolide Memo that Oakwood sent to Aurobindo and AuroMedics as part of the discussions related to the potential business venture, and the information and data that Dr. Thanoo brought to Defendants. This unpermitted use by Aurobindo and AuroMedics of Oakwood's trade secret information constitutes a breach of the Confidentiality Agreement.

85. Despite working for Aurobindo USA since April 2014 on microsphere systems technology and a products substantially similar to those developed in the Microsphere Project, Dr. Thanoo has never notified Oakwood of any inventions or improvements which he, either solely or jointly with others, has developed that are related to or would be useful in Oakwood's research, investigations, products, machines after his resignation, as required by the Inventions Agreement.

86. The facts alleged above establish that Defendants' misappropriated Oakwood's trade secrets. For example:

- a. Aurobindo approached Oakwood about a collaborative business relationship;
- b. Aurobindo led Oakwood to believe that it was actually interested in a business relationship in order to, among other things, gain access to Dr. Thanoo, the Microsphere Project, and the Leuprolide Memo;

- c. Aurobindo USA hired Dr. Thanoo;
- d. Within months of hiring Dr. Thanoo, Aurobindo announced in an investor call that AuroMedics formed a microsphere technology group in the U.S. in Dayton, New Jersey, where Dr. Thanoo works;
- e. Aurobindo, Aurobindo USA, and AuroMedics had no prior microsphere technology experience;
- f. Dr. Thanoo is engaged in the same work for Aurobindo USA that he worked on at Oakwood;
- g. Within a year or two of hiring Dr. Thanoo, Aurobindo announced on several investor calls that it developed four peptide-based microsphere products;
- h. Aurobindo's 2016-2017 annual report confirms that it "forayed" into "specialty injection products";
- i. During a May 2017 investor presentation, Aurobindo confirmed that the "microsphere technology based specialty injection products" are being developed at the Dayton, New Jersey, facility where Dr. Thanoo works; and
- j. As of March 7, 2019, Defendants are actively soliciting scientists to work under Dr. Thanoo on "sustained released injectable formulations."

87. Defendants' misappropriation of Oakwood's trade secrets and other wrongful activities in violation of their perspective agreements with Oakwood have caused Oakwood to suffer irreparable harm.

88. For example, and among things, the fact that Defendants have publicly announced that they are developing, and have made substantial progress in developing microsphere-based products, significantly reduces Oakwood's ability to partner with other companies, or to raise

financing to develop its own products, because potential partners or investors will now view Oakwood's competitive advantage to be significantly lower.

89. Defendants' actions and announcements have caused, and continue to cause, economic harm Oakwood.

90. Unless Defendants are enjoined from disclosing and using Oakwood's Confidential Information and Trade Secrets and from otherwise violating their agreements with Oakwood, Defendants will continue to cause Oakwood great and irreparable competitive harm.

CAUSES OF ACTION

Count I

Misappropriation of Trade Secrets Defend Trade Secrets Act of 2016 – 18 U.S.C. § 1832, *et seq.* (All Defendants)

91. Oakwood incorporates by reference the statements and allegations previously set forth in its Complaint as if fully rewritten herein.

92. Dr. Thanoo possesses trade secret information belonging to Oakwood including, but not limited to, its Confidential Information and Trade Secrets and trade secret information related to the Microsphere Project, by virtue of Dr. Thanoo's employment with Oakwood and his use of a personal email account to receive trade secret information related to the Oakwood Products.

93. Aurobindo, AuroMedics and Aurobindo USA possess trade secret information belonging to Oakwood, including trade secret information related to the Microsphere Project, by virtue of Oakwood providing a copy of the Leuprolide Memo to Aurobindo and AuroMedics.

94. Oakwood's Confidential Information and Trade Secrets are directly related to the development, testing, and manufacturing of products that are intended for use in or sold by Oakwood through interstate or foreign commerce.

95. Oakwood's Confidential Information and Trade Secrets are not generally known and Oakwood takes reasonable steps to maintain confidentiality with respect to its trade secret material, including the information referenced above.

96. Oakwood derives independent economic value from its Confidential Information and Trade Secrets not being generally known to or readily ascertainable through proper means by another person who can obtain economic value from the disclosure or use of the information.

97. In his role as Vice President of R&D Injectables at Aurobindo USA, Dr. Thanoo has used and disclosed and is continuing to use and disclose Oakwood's Confidential Information and Trade Secrets including trade secret information related to the Microsphere Project, without authorization and in breach of his contractual obligations to Oakwood.

98. Aurobindo, AuroMedics and Aurobindo USA have used and disclosed and are continuing to use and disclose Oakwood's Confidential Information and Trade Secrets, including trade secret information related to the Microsphere Project and the Leuprolide Memo, without authorization and in breach of their contractual obligations to Oakwood.

99. Defendants' continued use and disclosure of Oakwood's trade secret information constitute imminent, immediate, and irreparable harm to Oakwood.

100. Defendants have misappropriated Oakwood's trade secret information and, unless restrained, will continue to misappropriate Oakwood's trade secrets.

101. Oakwood has sustained damages and injury exceeding the principal sum of \$75,000 as a direct and proximate result of Defendants' misappropriation of Oakwood's trade secret information.

102. Defendants misappropriated Oakwood's trade secret information willfully and maliciously, entitling Oakwood to recover attorneys' fees from Dr. Thanoo pursuant to 18 U.S.C.

§ 1836(b)(3)(D) and punitive or exemplary damages from Dr. Thanoo pursuant to 18 U.S.C. § 1836(b)(3)(C).

Count II
Misappropriation of Trade Secrets
New Jersey Trade Secrets Act - NJ Rev Stat § 56:15-1 *et seq.*
(All Defendant)

103. Oakwood incorporates by reference the statements and allegations previously set forth in its Complaint as if fully rewritten herein.

104. Dr. Thanoo possesses trade secret information belonging to Oakwood including, but not limited to, its Confidential Information and Trade Secrets and its trade secret information related to the Microsphere Project, by virtue of Dr. Thanoo's employment with Oakwood and his use of a personal email account to receive trade secret information related to the Oakwood Products.

105. Aurobindo, AuroMedics and Aurobindo USA possess trade secret information belonging to Oakwood, including trade secret information related to the Microsphere Project, by virtue of Oakwood providing a copy of the Leuprolide Memo to Aurobindo and AuroMedics.

106. Oakwood's Confidential Information and Trade Secrets are not generally known and Oakwood takes reasonable steps to maintain confidentiality with respect to its trade secret material, including the information referenced above.

107. In his role as Vice President of R&D Injectables at Aurobindo USA, Dr. Thanoo has used and disclosed and is continuing to use and disclose Oakwood's Confidential Information and Trade Secrets including trade secret information related to the Microsphere Project without authorization and in breach of his contractual obligations to Oakwood.

108. Aurobindo, AuroMedics and Aurobindo USA have used and disclosed and are continuing to use and disclose Oakwood's Confidential Information and Trade Secrets, including

trade secret information related to the Microsphere Project and the Leuprolide Memo, without authorization and in breach of their contractual obligations to Oakwood.

109. Aurobindo, AuroMedics and Aurobindo USA acquired and used Oakwood's trade secrets knowing or having reason to know (i) the Oakwood's trade secrets were acquired through improper means; and/or (ii) that their knowledge of the trade secrets was derived from or through a party (Dr. Thanoo) who owed a duty to Oakwood to maintain the secrecy and limit the use of said trade secrets.

110. Aurobindo, AuroMedics and Aurobindo USA's microsphere products are based, at least in part, on Oakwood's trade secrets acquired through improper means through Dr. Thanoo.

111. Defendants have misappropriated and used Oakwood's trade secrets and/or inevitably will misappropriate and use said trade secrets, in violation of the laws of the State of New Jersey and similar laws of other states.

112. Defendants continued use and disclosure of Oakwood's trade secret information constitute imminent, immediate, and irreparable harm to Oakwood.

113. Defendants misappropriated Oakwood's trade secret information and, unless restrained, Oakwood will continue to misappropriate Oakwood's trade secret information.

114. Oakwood has sustained damages and injury exceeding the principal sum of \$75,000 as a direct and proximate result of Defendants' misappropriation of Oakwood's trade secret information.

115. Defendants misappropriated Oakwood's trade secrets willfully and maliciously, entitling Oakwood to recover attorneys' fees from Defendants pursuant to NJ Rev Stat § 56:15-6 and punitive or exemplary damages from Defendants pursuant to NJ Rev Stat § 56:15-4(b).

Count III
Breach of Contract – Inventions Agreement
(Defendant Dr. Thanoo)

116. Oakwood incorporates by reference the statements and allegations previously set forth in its Complaint as if fully rewritten herein.

117. Dr. Thanoo and Oakwood entered into the Inventions Agreement, a valid and enforceable contract.

118. The Inventions Agreement requires Dr. Thanoo to “fully and promptly disclose to Oakwood...all inventions and improvements...for twenty-four months (24) after the termination of such employment which relates to or are useful in the business, research, investigations, products, machines, and all lawful interests and activities of Oakwood.” (*See Exhibit A*).

119. Dr. Thanoo has worked with Aurobindo USA on the development of microsphere technology and on the development of a products substantially similar to those developed in the Microsphere Project since his resignation from Oakwood in April 2014. Despite that, Dr. Thanoo has not provided Oakwood with notification of any inventions or improvements following his resignation or the twenty-four (24) months thereafter which relates to or would be useful to Oakwood.

120. By failing to notify Oakwood of all inventions and improvements which relate to the business, research, investigations, products, machines, and all lawful interests and activities of Oakwood, Dr. Thanoo breached the Inventions Agreement he signed on November 24, 1997.

121. Unless restrained by the Court, Dr. Thanoo will continue his unlawful acts.

122. As a direct and proximate result of Dr. Thanoo’s breaches, Oakwood sustained damages.

123. The damages to Oakwood resulting from Dr. Thanoo's breaches of the Inventions Agreement will be difficult if not impossible to ascertain, but in any event they will exceed \$75,000.

Count IV
Breach of Contract – Non-Disclosure Agreement
(Defendant Dr. Thanoo)

124. Oakwood incorporates by reference the statements and allegations previously set forth in its Complaint as if fully rewritten herein.

125. Dr. Thanoo and Oakwood entered into the Non-Disclosure Agreement, a valid and enforceable agreement.

126. Under the terms of the Non-Disclosure Agreement, Dr. Thanoo had an "obligation to refrain from disclosing Oakwood Laboratories' confidential and proprietary information and to refrain from using it for the benefits of any other person or entity without the permission of Oakwood Laboratories." (*See* Exhibit B). This obligation remained even after the termination of Dr. Thanoo's employment relationship with Oakwood.

127. As described above, Dr. Thanoo breached the Non-Disclosure Agreement by disclosing, using, and misappropriating Oakwood's Confidential Information and Trade Secrets, including trade secret information related to the Microsphere Project, in conjunction with Aurobindo, AuroMedics, and Aurobindo USA to develop a products competitive with those developed in the Microsphere Project. By engaging in such wrongful conduct, Dr. Thanoo has disclosed and continues to disclose Oakwood's Confidential Information and Trade Secrets in violation of the Non-Disclosure Agreement.

128. The Non-Disclosure Agreement is reasonable and serves to protect Oakwood's Confidential Information and Trade Secrets, customer relationships and goodwill, and its

investment in training Dr. Thanoo. Enforcement of the Non-Disclosure Agreement will not injure the public in any respect.

129. Unless restrained by the Court, Dr. Thanoo will continue his unlawful acts.

130. As a direct and proximate result of Dr. Thanoo's breaches, Oakwood sustained damages.

131. The damages to Oakwood resulting from Dr. Thanoo's breaches of the Non-Disclosure Agreement will be difficult if not impossible to ascertain, but in any event they will exceed \$75,000.

Count V
Breach of Contract – Confidentiality Agreement
(Defendants Aurobindo and AuroMedics)

132. Oakwood incorporates by reference the statements and allegations previously set forth in its Complaint as if fully rewritten herein.

133. Oakwood, AuroMedics, and Aurobindo entered into the Confidentiality Agreement, a valid and enforceable agreement.

134. The Confidentiality Agreement provides, in pertinent part:

[AuroMedics and Aurobindo] will use the Confidential Information of [Oakwood] solely for the Permitted Use and for no other purpose. [AuroMedics and Aurobindo] will keep all Confidential Information of [Oakwood] secret and confidential and will not reproduce, distribute, disclose, make available, or otherwise disseminate Confidential Information...

(Exhibit C, ¶ 3).

135. On December 3, 2013, Oakwood provided to Aurobindo and AuroMedics the Leuprolide Memo, which contained Oakwood's trade secret information related to the Microsphere Project.

136. Upon information and belief, Aurobindo, AuroMedics, and Aurobindo USA are developing or have developed a product substantially similar to and competitive with Oakwood's Microsphere Project. Aurobindo, AuroMedics, and/or Aurobindo USA could not develop this product without Oakwood's trade secret information related to the Microsphere Project and the Leuprolide Memo and other information disclosed to them by Oakwood during discussions related to the potential business venture. This unpermitted use by Aurobindo and AuroMedics of Oakwood's Confidential Information and Trade Secrets constitutes a breach of the Confidentiality Agreement.

137. Pursuant to the Confidentiality Agreement, "[i]f a party brings a legal action against the other arising out of this Agreement, then the prevailing party will be entitled, to the fullest extent permitted by law, to recover its reasonable attorneys' fees and all other expenses and costs incurred in connection with such action or proceeding." (Exhibit C, ¶ 13).

138. As a direct and proximate result of Aurobindo and AuroMedics' breaches, Oakwood sustained damages.

139. The damages to Oakwood resulting from Aurobindo and AuroMedics' breaches of the Confidentiality Agreement will exceed \$75,000, plus reasonable attorneys' fees and all other expenses and costs incurred.

Count VI
Tortious Interference with Contractual Relationship
(Defendants Aurobindo and Aurobindo USA)

140. Oakwood incorporates by reference the statements and allegations previously set forth in its Complaint as if fully rewritten herein.

141. Oakwood had valid a Non-Disclosure Agreement with Dr. Thanoo.

142. Under the terms of the Non-Disclosure Agreement, Dr. Thanoo had an “obligation to refrain from disclosing Oakwood Laboratories’ confidential and proprietary information and to refrain from using it for the benefits of any other person or entity without the permission of Oakwood Laboratories.” (*See* Exhibit B).

143. Oakwood is informed and believes that Aurobindo USA and Aurobindo were aware of the existence of that agreement.

144. Aurobindo USA and Aurobindo intentionally procured breaches of Dr. Thanoo’s Non-Disclosure Agreement. Upon information and belief, Aurobindo, AuroMedics, and/or Aurobindo USA is developing a products substantially similar to and competitive with those developed in Oakwood’s Microsphere Project. Aurobindo, AuroMedics, and/or Aurobindo USA could not develop this product without Dr. Thanoo’s assistance and his use of Oakwood’s Confidential Information and Trade Secrets, in violation of his Non-Disclosure Agreement.

145. Aurobindo USA and Aurobindo’s interference with Dr. Thanoo’s Non-Disclosure Agreement was without justification.

146. Aurobindo USA and Aurobindo acted with malice toward Oakwood when tortiously interfering with Dr. Thanoo’s Non-Disclosure Agreement with Oakwood.

147. Oakwood sustained damages exceeding \$75,000 as a direct and proximate result of Aurobindo USA and Aurobindo’s tortious interference with Dr. Thanoo’s Non-Disclosure Agreement with Oakwood.

WHEREFORE, Oakwood Laboratories, L.L.C. respectfully requests that this Court enter judgment against Defendants Dr. Bagavathikanun Thanoo, AuroMedics Pharma LLC, Aurobindo Pharma U.S.A., Inc., and Aurobindo Pharma Ltd. and in favor of Oakwood Laboratories, L.L.C. as follows:

- a. Compensatory damages in an amount exceeding the principal sum of \$75,000, to be proven at trial;
- b. Royalty payments;
- c. Punitive or exemplary damages;
- d. A preliminary and permanent injunction enjoining and restraining Defendants;
- e. Reasonable attorneys' fees and costs incurred by virtue of this action; and
- f. Such other and further relief as the Court may deem appropriate.

JURY DEMAND

Plaintiff Oakwood Laboratories, L.L.C., hereby demands a trial by jury, by the maximum number of jurors permitted by law, on all issues so triable herein.

Dated: March 11, 2019

BENESCH, FRIEDLANDER, COPLAN
& ARONOFF, LLP

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